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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0713]

Draft Guidance for Industry on Submitting Debarment Certification Statements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Submitting Debarment Certification Statements. " The draft guidance addresses the most commonly asked questions about debarment certification statements and information requirements under the Federal Food, Drug, and Cosmetic Act (the act) and is intended to assist in the submission of applications for human, animal, and biologic drug products, export applications for certain unapproved products, and supplements to certain drug product applications.

DATES: Written comments on the draft guidance document may be submitted by (*insert date 60 days after date of publication in the* **Federal Register).** General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at http: //www.fda.gov/cder/guidance/index .htm or http: //www.fda.gov/cber/guidelines.htm. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

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FOR FURTHER INFORMATION CONTACT: Leanne Cusumano, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594-2041.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance entitled ''Submitting Debarment Certification Statements. " Section 306(k) of the act (21. U.S.C. 335a(k)) states that drug product applications are to include a certification that the applicant did not and will not use in any capacity the services of any person who has been debarred under sections 306(a) or (b) of the act. Additionally, section 306(k) of the act requires that abbreviated new drug applications (ANDA 's) and supplements to ANDA's providing for a *different or additional use* and submitted on or after June 1, 1992, contain a list of all convictions of the applicant and affiliated persons responsible for the development or submission of such application that have occurred within the last 5 years and for which a person can be debarred.

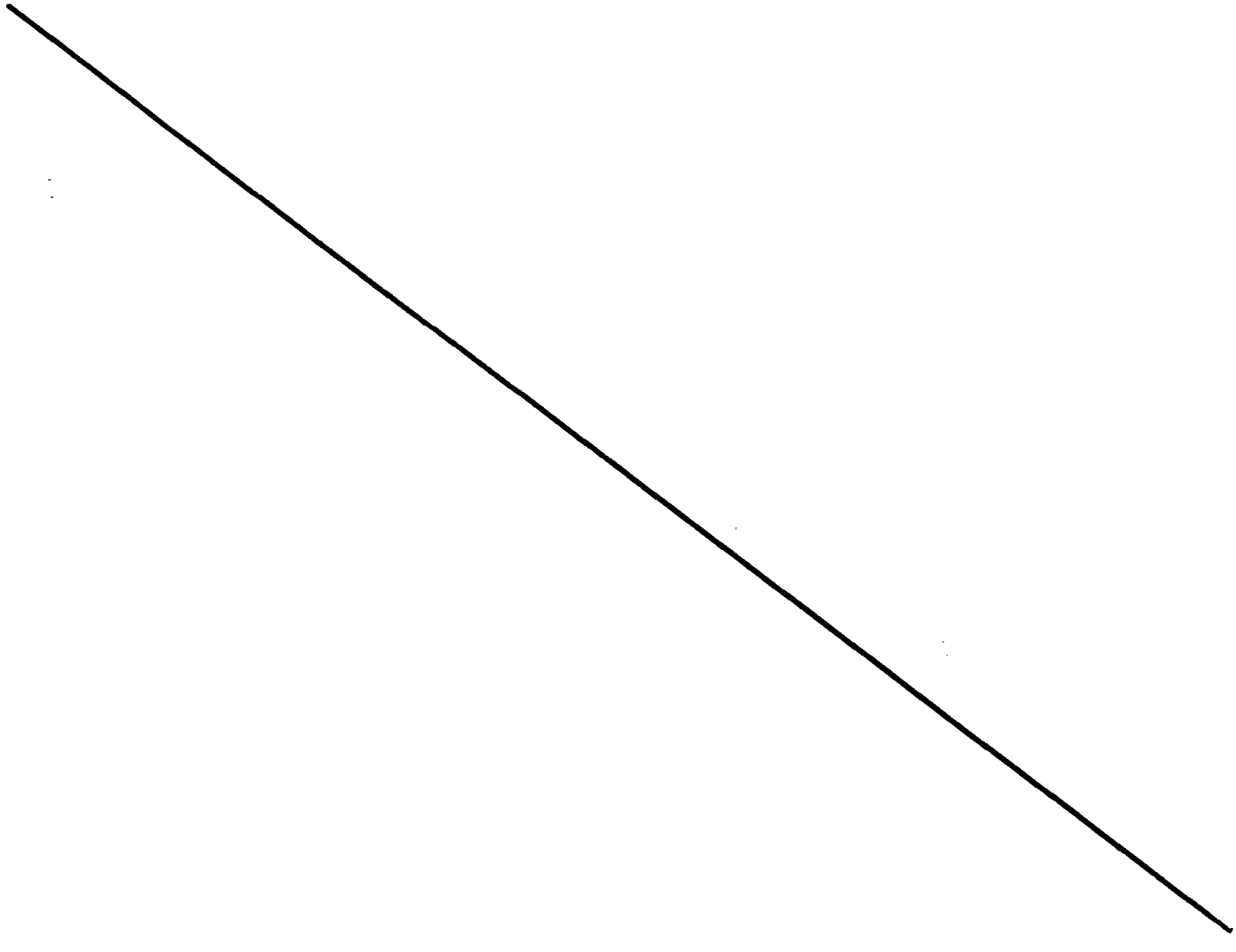
Since section 306(k) of the act became effective in 1992, FDA has received a number of requests for clarification. This draft guidance addresses the most commonly asked questions about the certification and information requirements and should be helpful to those submitting the following drug product applications to FDA: (1) New drug applications, (2) ANDA's, (3) new animal drug applications, (4) abbreviated new animal drug applications, (5) export applications for certain unapproved products, (6) biological license applications, and (7) supplements to certain drug product applications. The draft guidance was prepared by the Debarment Task Force at FDA.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on debarment certification statements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Submit written requests for single copies of the draft guidance entitled "Submitting Debarment Certification Statements" to the Drug Information Branch (HFD-21O), Center for Drug Evaluation

and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1 448; or the Communications and Education Branch (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish PI., Rockville, MD 20855. Requests should be identified with the docket number found in brackets in the heading of this document. Send one self-addressed adhesive label to assist the office in processing your request.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number



found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 4, 1998

William B. Schultz
Deputy Commissioner for Policy

[FR Dec. 98-???? Filed ??-??-98; 8:45 am]

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